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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO.     |
|--|-------------|----------------------|---------------------|----------------------|
| 10/071,722   | 02/07/2002  | Andrew J.S. Evans    | 08565.136           | 3152                 |
| 23483  | 7590        | 09/08/2005           | EXAMINER            |                      |
| WILMER CUTLER PICKERING HALE AND DORR LLP<br>60 STATE STREET<br>BOSTON, MA 02109 |             |                      |                     | WIEKER, AMANDA FLYNN |
|  |             | ART UNIT             |                     | PAPER NUMBER         |
|  |             |                      |                     | 3743                 |

DATE MAILED: 09/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                              |                  |  |
|------------------------------|------------------------------|------------------|--|
| <b>Office Action Summary</b> | Application No.              | Applicant(s)     |  |
|                              | 10/071,722                   | EVANS ET AL.     |  |
|                              | Examiner<br>Amanda F. Wieker | Art Unit<br>3743 |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 27 June 2005.  
 2a) This action is FINAL.                  2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-9 and 15-20 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-9 and 15-20 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 07 February 2002 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-6, 9, 15-16 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Great Britain Patent Specification Number 1,499,807 to Ring.

Regarding claim 1, Ring discloses an orthotic strut component (any of 2, 3, 5) for an orthosis comprising the combination of a ductile metallic tube (21) having a transverse cross-section of elongate shape (see Figure 2) and an internal core (22) of substantially uncured plastics and fibre composite material which is a close fit within the tube (again, see Figure 2). Regarding claim 2, the tube is made of annealed aluminum alloy. Regarding claims 3, 5 and 18, the cross-section of the tube is of an oblong-shape having substantially straight sides and rounded ends. Regarding claims 4 and 5, the cross-sections of the strut and tube are substantially constant over the major part of the length of the strut component (see Figure 1 for example). Regarding claim 9, after the strut is fitted to a user, the core is cured (lines 90-92).

Regarding claim 16, the internal cross-sectional area of the tube is substantially fully occupied by the internal core (see Figure 2). Regarding claim 19, Ring discloses an orthosis (see Figure 1) comprising a strut component (any of 2, 3, 5) in the form of combination of a ductile metallic tube (21) having a cross-section of elongate shape (see Figure 2) and an internal core (22) of substantially cured plastics and fibre composite material which is a close fit within the tube

(again, see Figure 2). Regarding claim 20, Ring discloses that the struts can be shaped to fit the user (i.e., “bent”; see lines 84-86). Ring discloses the invention substantially as claimed, however, Ring does not specify the dimensions of the strut.

At the time the invention was made, however, it would have been an obvious matter of design choice to a person of ordinary skill in the art of orthotics to have provided the struts with the claimed length, wall thickness, internal circumference (and necessarily K value), cross-sectional ratio and thickness, because Applicant has not disclosed that such dimensions provide an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Ring’s orthotic struts, and Applicant’s invention, to perform equally well with either the dimensions shown by Ring or the claimed dimensions because both dimensions would perform the same function of securing to the lower leg of a user and providing support for the lower limbs. It would have been obvious to one skilled in the art of orthotics, at the time the invention was made, to have discovered the ideal dimensions of the struts, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

Therefore, it would have been *prima facie* obvious to modify Ring to obtain the invention as specified in claims 1-6, 9, 15-16 and 18-20 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Ring.

3. Claims 7, 8 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ring in view of U.S. Patent Number 5,364,095 to Easton et al.

Ring discloses the previously described orthosis and orthotic strut component, wherein the strut comprises an aluminum tube having a cross-section of elongate shape and an internal

core of uncured plastics and fibre composite material. Ring does not specify an expansion agent within the composite material.

Easton et al. disclose a component capable of being used as a strut, wherein the component includes a ductile aluminum tube and an internal core of uncured plastics and fibre composite material. Easton et al. specify that the internal core comprises an inner kernel made of a heat-activated expansion agent extending lengthwise through the strut surrounded by a plastics and fibre composite material, wherein the expansion agent is a foaming agent which is formed as one or more longitudinally extending strings of material such as an epoxy resin (column 3, lines 9-22), to provide additional rigidity to the component upon heating.

It would have been obvious to one skilled in the art at the time the invention was made to have provided the orthosis and orthotic strut disclosed by Ring, wherein an inner kernel of expansion agent is located within the internal core, as taught by Easton et al., to provide additional rigidity to the component when the component is heated.

*Response to Arguments*

4. Applicant's arguments with respect to claims 1-9 have been considered but are moot in view of the new ground(s) of rejection.

*Conclusion*

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until

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after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda F. Wieker whose telephone number is 571-272-4794. The examiner can normally be reached on Monday-Thursday, 7:30 - 5:00 and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amanda F. Wieker  
Examiner  
Art Unit 3743

afw

Henry Bennett  
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